K033986

MAR 2 9 2004

APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

MLT – 1000 IR Laser System

I. Applicant:

Medical Laser Therapeutics LP
1019 Dragon Street
Dallas, Texas 75207
1 214 748 - 1088

Contact Person: James Nairne

Date Prepared: December 22, 2003

II. Device Name

Proprietary Name:	MLT – 1000 IR Laser System
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The MLT - 1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

IV. Predicate Devices

The MLT-1000 IR Laser System is substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include, but are not limited to, the Bales Scientific, Inc. Photonic Stimulator (K974468), Light Force Therapy, Inc. Super Nova and Acubeam Systems (K001179), the Meditech International Inc BioFlex Professional Therapy System (K023621) and the Spectrum Laser & Technologies, Inc. Neurolase Series (K032787).

V. Description of the Device

The MLT - 1000 IR Laser System is an innovative, safe, easy to use, hand-held, non-invasive therapeutic device that provides continuous heat therapy. The System consists of a Control Unit that houses the electronics and controls and a treatment probe hand piece that delivers the infrared energy.

VI. Summary of the technical characteristics of the MLT - 1000 IR Laser System to the referenced predicate devices

The MLT - 1000 IR Laser System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. These devices utilize infrared and visible laser diodes to generate topical heating for the purpose of elevating tissue temperatures for temporary relief of muscle and joint pain.

VII. Testing

Testing of the MLT – 1000 IR Laser System will include functional performance testing and electrical safety testing in accordance with all applicable standards for this type medical device.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the MLT-1000 has the same intended uses, with similar functional and performance characteristics. The System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Federal Food and Drug Administration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 9 2004

Medical Laser Therapeutics LP
c/o Ms. M. Joyce Heinrich
Texas Applied Biomedical Services
12101-A Cullen Boulevard
Houston, Texas 77047

Re: K033986
Trade/Device Name: MLT – 1000 IR Laser System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: II
Product Code: ILY
Dated: December 22, 2003
Received: December 30, 2003

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX C

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): Pending K033986

Device Name:

MLT - 1000 IR Laser System

Indications for Use:

The MLT - 1000 IR Laser System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ **OR** **Over the Counter Use:**
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

(Division Sign-Off) Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number _____

510(k) Number K033986